

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**84321**

**MEDICAL REVIEW**

*Salman Copy*

REVIEW OF RESUBMISSION PPL

DATE COMPLETED: 10-11-74

ANDA # 84-321

F.R. DATE: 7-28-72

CO. NAME: Beecham-Massengill Pharm.  
Bristol, TN 37620

NAME OF DRUG: Generic: Probenecid and Colchicine Tablets

DATE OF SUBMISSION:

TYPE OF SUBMISSION: Resubmission (reply to F.D.A. letter 7-19-74)

CLINICAL EVALUATION:

1. Review of Studies:

Pertinent data is to be reviewed by the chemist.

Bioavailability requirement: Required

Rationale for % excess of colchicine presented: Level of  
% excess of colchicine proposed for present formulation.

2. Review of Labeling:

(a) Container Labels: Satisfactory

F.P.L.            Tablets   B ottles of 100  
                  Probenecid 0.5 gm  
                  Colchicine 0.5 mg

(b) Insert Labeling: Satisfactory  
                      Aug. 74

CONCLUSION:

Labeling is satisfactory for the safe and effective use  
of this product.

RECOMMENDATION: The firm is to be so informed.

cc: Dup  
HFD-107  
VVKarusaitis/rt/10-16-74

/S/  
V. V. Karusaitis, M.D.

REVIEW OF ANDA

DATE COMPLETED: 6-14-74

ANDA #: 84-321

CO. NAME: Beecham-Massengill Pharm.  
Bristol, TN 37620

F.R. DATE: 7-28-74

NAME OF DRUG: Probenecid and Colchicine Tablets

DATE OF SUBMISSION: 5-16-74

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

\* Reference product "Col Benemid" contains 0.5 g. of each drug; submitted product contains 0.525 g. of colchicine.

1. Review of Studies: Pertinent data is to be reviewed by the chemist.

Bioavailability status: Required.

2. Review of Labeling:

a) Container labels: Satisfactory. Bottles of 100  
Container labels state each tablet contains: Probenecid 0.5 gm  
Colchicine 0.5 gm  
yet, composition of tablet states 0.525 gm for colchicine.

b) Insert labeling: Satisfactory

CONCLUSION: Strength of tablet requires clarification; otherwise labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

7/5/74  
V.V. Karusaitis, M.D.

cc:  
Dup  
HFD-107  
VVKarusaitis/wlb/6-17-74